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ATTORNEY'S DOCKET NUMBER U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE FORM PTO-1390 (Modified) REV. 7-2005) PB60536USW TRANSMITTAL LETTER TO THE UNITED STATES U.S. APPLICATION NO. (If known, see 37 CFR 1.5) DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 PRIORITY DATE CLAIMED INTERNATIONAL FILING DATE INTERNATIONAL APPLICATION NO. 14 October 2003 12 October 2004 PCT/US2004/033521 TITLE OF INVENTION Process for Preparing a Co-Precipitate of a Non-Crystalline Solid Drug Substance APPLICANT(S) FOR DO/EO/US BARRETT, Roger; WARD, Richard, Anthony Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), 3 (9) and (24) indicated below. The US has been elected (Article 31). X A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) 5. is attached hereto (required only if not communicated by the International Bureau). a. 🗆 has been communicated by the International Bureau. b. 🗆 is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). 6. is attached hereto. a. 🛚 has been previously submitted under 35 U.S.C. 154(d)(4). b. 🗆 Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) 7. are attached hereto (required only if not communicated by the International Bureau). a. 🗀 have been communicated by the International Bureau. b. 🗆 have not been made; however, the time limit for making such amendments has NOT expired. C. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 8. An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 9. An English language translation of the annexes to the International Preliminary Examination Report under PCT 10. Article 36 (35 U.S.C. 371 (c)(5)). A copy of the International Preliminary Examination Report (PCT/IPEA/409). 11. A copy of the International Search Report (PCT/ISA/210). Items 13 to 23 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 13. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 14. 15. A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. 16. 17. A substitute specification. \boxtimes A power of attorney and/or change of address letter. 18. \Box A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 19. A second copy of the published International Application under 35 U.S.C. 154(d)(4). 20. A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 21. \boxtimes 22. Express Mail Label No. EV 332064632 US

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. INTERNATIONAL APPLICATION NO. U.S. APPLICATION NO (if known, see 37 CFR 1.5) PB60536USW PCT/US2004/033521 Other items or information: 23. a) PCT Cover Page b) PCT Request **PTO USE CALCULATIONS** The following fees have been submitted: \$300.00 \$300 24. 🖾 Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report \$200.00 prepared by IPEA/US indicates all claims satisfy provisions of PCT Article \$0 \$200 Search fee (37 CFR 1.492(b)) If the written opinionof the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4). . . \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the \$400.00 as an International Searching Authority. \$100 International Search Report prepared by an ISA other than the US and provided to the

TOTAL OF 24, 25 and 26 =
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.

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